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10/036,568	11/07/2001	Tracy Willson	11373Z	4029

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Garden City, NY 11530

EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

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03/19/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/036,568	Applicant(s) WILLSON ET AL.	
	Examiner NIRMAL S. BASI	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37, 42, 43, 47 and 52-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 37, 42, 43, 47, 52 and 54 is/are allowed.
- 6) ☒ Claim(s) 53 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 December 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed 12/30/8 has been entered. Claims 37, 42-43, 47 and 52-55 are pending in the application and are examined below. Applicant's arguments have been fully considered and are addressed below:

Drawings

2. The drawings for Figure 7 filed 12/30/08 is approved by the Examiner.
3. The amendment filed 7/2/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:
- 4.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 53 and 55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim incorporates new matter, "isolated polypeptide comprising amino acids 28-342 of SEQ ID NO:4 or comprising an amino acid sequence having at least 95% identity with amino acids 28-342 of SEQ ID NO:4". Said new matter is not supported by the original disclosure.

(1) The specification does not teach an isolated polypeptide that consists of residues 28-342 of SEQ ID NO: 4.

(2) The specification does not teach derivatives of an IL-13 receptor α -chain that comprises residues 28-342 of SEQ ID NO: 4.

Applicants' arguments filed 12/30/08 and the Declaration of Angel Lopez have been fully considered but they are not found persuasive.

In the response, Applicants and the Declaration of Angel Lopez argue that the amended claim is fully supported by the specification and does not introduce new matter. Applicants argue that amino acids 28-342 of SEQ ID NO: 4 is based on the alignment between the human and murine sequences and on the disclosure of a murine soluble form composed of amino acids 27-340 of SEQ ID NO: 2.

Applicants' arguments and the Declaration of Angel Lopez have been fully considered but are not found persuasive. The specification does not teach that a derivative consisting of residues 28-342 of SEQ ID NO: 4 (human sequence) is part of the claimed invention. Furthermore, the specification does not even teach that a derivative consisting of the corresponding residues (27-340) of the mouse sequence (SEQ ID NO: 2) is part of the claimed invention. The specification teaches that the invention includes nucleic acids encoding a part of SEQ ID NO: 2 (pg 4) or SEQ ID NO: 4 (pg 5), but does not point to any particular part of either sequence on these pages. The specification further teaches that a recombinant IL-13 receptor α -chain may be in soluble form, but does not teach any specific residues for this soluble form. The skilled artisan would recognize that a "soluble form" is a genus that includes any variant of SEQ ID NO: 4 that is mutated to render the protein soluble (such as by deleting all or part of the transmembrane domain), and thus does not refer to any specific sequence. Example 12 provides a single example of a soluble receptor derived from SEQ ID NO: 2 that is "[t]he mature extracellular part of the NR4 coding region (Thr27 to Thr344)". While this specific example may provide support for a derivative consisting of the exact corresponding residues of the human sequence (Thr28-Thr346), it does not provide support for either a slightly shorter form of the murine (residues 27-340 of SEQ ID NO: 2) or the corresponding human (28-342 of SEQ ID NO: 4) sequences. There is nothing in the specification directing the skilled artisan to these slightly shorter sequences. The specification does not contain any teachings indicating that a derivative consisting of the

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specific residues corresponding to the isolated extracellular domain of either protein is part of the invention. The only teaching in the specification regarding the use of the extracellular domain of the protein is the specific example in Example 12.

Applicant is required to cancel the new matter in the reply to this Office Action.

5. Claims 37, 42, 43, 47, 52 and 54 are allowable

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIRMAL S. BASI whose telephone number is (571)272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nirmal S. Basi/
Examiner, Art Unit 1646

/Michael Pak/
Primary Examiner, Art Unit 1646